IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Before the Board of Patent Appeals and Interferences

Atty Dkt. 1331-338 C#

T.C. / Art Unit: 1653

Examiner: K.C. Carlson Serial No. 09/839,164 Filed: April 23, 2001

Date: August 16, 2004

PROLIFERATION AND USES THEREOF Title: INHIBITOR OF STEM CE

Mail Stop Appeal Brief - Patents

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

NOTICE OF APPEAL

In re Patent Application

KOZLOV et al.

Sir:

☐ Correspondence Address Indication Form Attached.

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the Examiner twice/finally rejecting (\$330.00) applicant's claim(s).

An appeal **BRIEF** is attached in triplicate in the pending appeal of the 0.00 above-identified application (\$ 330.00)

-\$ (Credit for fees paid in prior appeal without decision on merits

A REPLY BRIEF is attached in triplicate under Rule 193(b) (no fee)

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months; \$1480.00/4 months) **SUBTOTAL** \$

0.00 -\$(Applicant claims "Small entity" status, enter ½ of subtotal and subtract "Small entity" statement attached.

SUBTOTAL 0.00

-\$(

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Less month extension previously paid on

> **TOTAL FEE ENCLOSED \$** 0.00

0.00)

THW AF

Any future submission requiring an extension of time is hereby stated to include a petition for such time extension. The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our **Account No. 14-1140.** A duplicate copy of this sheet is attached.

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GRT:ap

NIXON & VANDERHYE P.C.

By Atty: Gary R. Tanigawa, Reg. No. 43,180

Signature:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

KOZLOV et al.

Appln. No. 09/839,164

Filed: April 23, 2001

Confirmation No.: 6786

Atty. Ref.: 1331-338

T.C. / Art Unit: 1653

Examiner: K.C. Carlson

FOR: INHIBITOR OF STEM CELL PROLIFERATION AND USES THEREOF

AUG 1 6 200

REPLY BRIEF UNDER 37 CFR § 1.193

August 16, 2004

Mail Stop Appeal Brief – Patents Hon. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Appellants submit this Reply Brief (in triplicate) within two months of the mailing of the Examiner's Answer. Reversal of the Examiner's final claim rejections by the Board of Patent Appeals and Interferences (the "Board") is respectfully requested.

As an initial matter, it is noted that Appellants' Brief contained a typographical error on page 5: "millimeter" should have been --milliliter-- in both occurrences of the first full paragraph. Millimeter is a unit of length, whereas milliliter is a unit of volume.

With regard to the Section 112, second paragraph, rejection the Examiner asks, "Is Appellant implying that 0.1 mg of globin chain in a room full of pharmaceutical carrier is the same as 0.1 mg of globin chain in a milliliter of pharmaceutical carrier?" (Examiner's Answer, page 4). Appellants have not stated or implied that such solutions are the same in all respects. However both solutions would read on the claims because the claims are not defined by their volumes. Appellants have chosen to define their inventtion by the <u>mass</u> of alpha and/or beta globin chain in the pharmaceutical composition. The Examiner also states, "It appears that Appellants may be wanting to administer 0.1 mg to 6 g of globin chain to a subject in a single dose " (Examiner's Answer, page 4). Appellants note that the claims on appeal are directed to a composition, not to a method of administration.

With regard to the Section 102 rejections the Examiner's Answer argues that "it is very plausible" that Tame et al. or Hoffmann et al. made their solutions in volumes of 10 ml, 100 ml or 1 liter, corresponding to 50 mg, 500 mg or 0.5 grams of globin based on a concentration of 5 mg/ml. Plausible perhaps, but not "necessarily present" as required for anticipation. Cf. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949,1951 (Fed. Cir. 1999), quoting *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). The Examiner's speculations as to the volumes made by Tame et al. or Hoffmann et al. do not substitute for the fact that the amount of globin they made is <u>not</u> taught in the cited references.

For the reasons discussed above, Appellants respectfully request that the claim rejections should be reversed by the Board. Appellants submit that the pending claims are in condition for allowance and earnestly request an early Notice to that effect.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:

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